

March 25, 2022

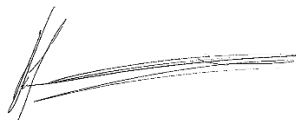
Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

Dear Dr. Tripathi,

The HIMSS Electronic Health Record Association (EHRA) member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using electronic health records (EHRs) and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable health information technology.

On behalf of our nearly 30 member companies, we appreciate the opportunity to provide input on opportunities to automate and reduce the burden associated with prior authorization workflow using the capabilities of interoperable health IT.

Sincerely,



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Chair, EHR Association
Cerner Corporation



David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

AdvancedMD
Allscripts
Athenahealth
BestNotes
Cerner Corporation
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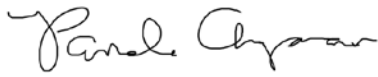
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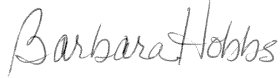
HIMSS EHR Association Executive Committee



Pamela Chapman
Experity



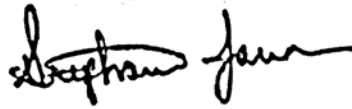
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Cherie Holmes-Henry
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Greenway Health



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About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS.

For more information, visit www.ehra.org.

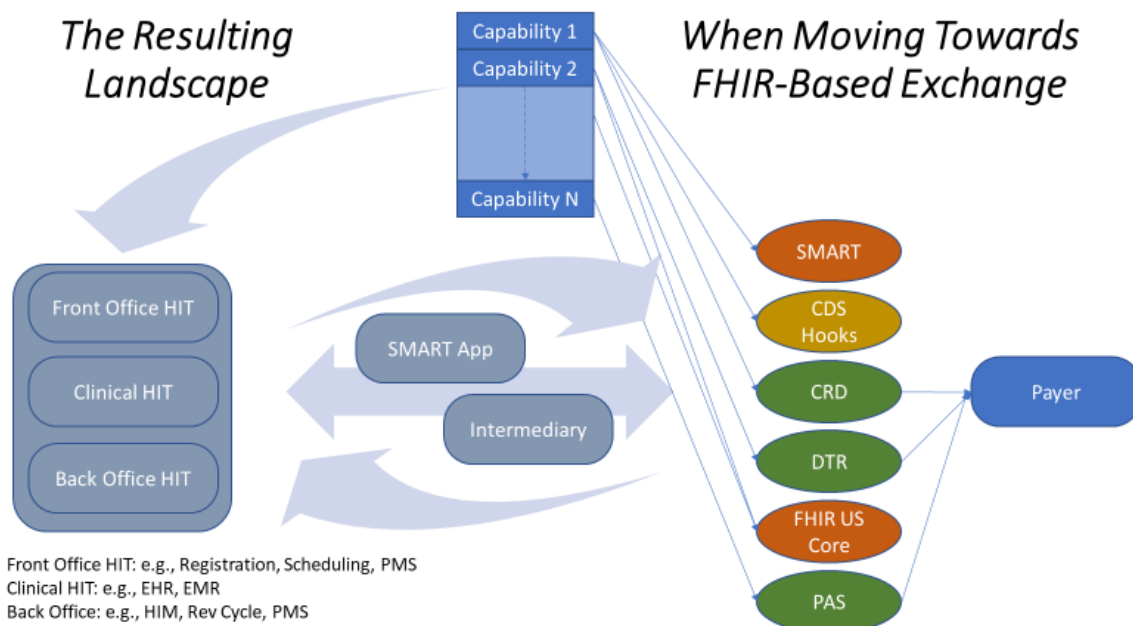
Electronic Health Record Association
Comments on the Request for Information: Electronic Prior Authorization
Standards, Implementation Specifications, and Certification Criteria

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General Considerations and Recommendations

Prior authorization is a complex process that requires collaboration across many domains both within an individual healthcare organization and with the dozens of health plans covering the organization's patients. Efforts to streamline prior authorization processes will require a significant amount of coordination and standardization across those stakeholders and the health IT tools they use. The three Implementation Guides (IG) under development by the Da Vinci Project – Coverage Requirements Determination (CRD), Documentation Templates and Rules (DTR), and the Prior Authorization Support (PAS) – provide a good starting point for outlining the general flow and interactions across modules and systems used by providers and health plans that will be needed for a full end-to-end prior authorization workflow. The Da Vinci Project's efforts to investigate functional requirements, build consensus on a technical approach, pilot, and iterate have resulted in significant progress toward the enablement of highly automated prior authorization workflows. Although these IGs show promise, they are not yet in a state of maturity that is sufficient for adoption in certification.

Additionally, because of the unique health IT needs of each provider organization, differences in how health IT products are developed, supported, and marketed by developers, and the current structure of ONC's certification program, it could be challenging to adopt criteria requiring the support of all three IGs in the future. Provider organizations have widely varying approaches to the adoption and deployment of health IT systems. Some use a single, integrated health IT solution that encompasses all of the functionality required to enable prior authorization. Others, typically larger provider organizations, may have capabilities for prior authorization and financial management distributed across multiple health IT solutions from different vendors. The following diagram illustrates a high-level perspective on the health IT landscape involved from a provider perspective.



For example, the trigger of a prior authorization workflow may start with a clinician using an order entry capability in an EHR, a scheduler creating an appointment, or a case manager working in their separate case management system. The collection of the necessary data to support a prior authorization request

may involve exporting records directly from an individual EHR, or could require documentation from multiple systems such as specialty-specific EHRs or repositories spanning multiple EHR systems using a health information management (HIM) application. This can also cause complexity when a plan's prior authorization requirements necessitate follow up for the submission of additional data. And lastly, once submitted, any responses that come back from the payer are of interest to not only the initiating user, but also back-office revenue cycle staff and patients.

Over the last couple of years, various configurations have been utilized to connect relevant health IT during Da Vinci connect-a-thons and initial pilot efforts. These highlighted the additional opportunity for SMART Apps to be used to take on many of the interactions that otherwise would be distributed across different types of health IT. Specifically, based on these experiences, the initiating system (EHR, scheduling, registration, or case management system) invokes the SMART App (using CDS Hooks automatically or even a simple SMART Launch), which in turn interacts with the payer (a specific one only, or any payer supporting CRD) to determine coverage requirements. The SMART App would then query the payer for the documentation requirements using the DTR specifications and then turn the CQL or questionnaire provided by the payer into one or more FHIR US Core API calls to the target data source. The data source would not have to support DTR, rather only the relevant FHIR US Core resources. The SMART App would enable gathering any data manually if it could not be obtained automatically and manage the follow-up until it submits the request using the PAS to the payer. Any additional follow-up would be orchestrated by the SMART App. Once the payer has approved/declined the authorization request and the SMART App receives this, it notifies the relevant parties.

Because of the complexity described above, boundaries delineating which health IT would support specific interactions are intentionally not prescribed within the respective Da Vinci guides. **Requiring certification to a full prior authorization workflow for provider-focused health IT is premature, considering both the variety of practical and valid configurations of health IT and the absence of clearly defined, more granular interaction sets within the respective guides. A phased and focused approach should be considered to advance capabilities across the relevant health IT. Healthcare providers should have the flexibility to choose which health IT solutions they use to meet the individual functional needs in the prior authorization workflows. If certification criteria for prior authorization are defined in the future, they should be at a functional requirement level, rather than requiring the support of a full end-to-end workflow within the certified product or for an entire Da Vinci Project prior authorization implementation guide. Health IT developers would then have the flexibility to choose which components of the prior authorization workflow are reasonable to support within their systems, without being forced to expand to offer additional products in new markets. We urge ONC not to allocate all provider-side interactions to one health IT solution only, whether an EHR, a practice management system, or any other system, but rather recognize the need for flexibility.**

At the same time, we recognize that it is important for providers to have certainty that their full health IT suite supports the entire prior authorization workflow. That is reminiscent of certification criteria in which the provider organization needed to ensure it had a "complete" solution across what may be multiple sources of health IT to have met CMS program participation requirements for use of "Certified EHR Technology" under Meaningful Use (now Promoting Interoperability). To provide a glidepath to enable the necessary flexibility on the health IT side and enable providers to ensure the relevant software support is properly available, **we suggest the following staged approach:**

Stage 1

1. Work with CMS to focus adoption and certification of CRD, DTR, and PAS implementation guides (as they exist) on the payer side and establish a clear implementation standard for any interactions with the payers supporting prior authorization.
2. Do not set certification criteria for provider-focused health IT until there is clarity on how specific functional needs supported by the IGs map to the various systems in use at healthcare organizations to support prior authorization, including certified EHRs, non-certified health IT, and SMART on FHIR Apps.
 - a. The presence of standardized payer APIs for prior authorizations will encourage health IT developers to determine how to best adopt the same standards as payers, but only for those interactions which the health IT performs.
 - b. ONC should make test harnesses available for the respective interactions that can be exercised individually.

Stage 2

1. Establish health IT certification criteria based on the matured and evolved interaction distributions across health IT, with the typical interaction sets documented clearly within each of the CRD, DTR, and PAS implementation guides.
2. Extend the provider functional requirement for prior authorization engagement with the use of certified health IT to support the prior authorization workflow. While there will be a progression and expansion of the basis of what health IT is certified, we strongly recommend that providers should be fully supported over time by a suite of certified health IT for the full prior authorization workflow.

We suggest that the initial focus of Stage 1 as outlined above should be on CRD and PAS interactions. The complexity of managing the DTR capabilities on the provider side, even when all carried out within one system, is substantial. There is a need to have full transparency of the data requirements for each service/item/procedure needing authorization to enable providers to effectively grant automated access to and gathering of the necessary data in their health IT. These complexities also include the adoption of data collection automation using CQL and/or Questionnaires, keeping in mind the large variety of payer plans and data requirements across those plans for the same services/items, the relevant workflow management needed for the transition from manual to fully automated data collection, and management of any follow-up requests for data. Once that has the opportunity to mature, either a Stage 1B is appropriate, or DTR may be blended in with Stage 2.

In this context, we provide the following detailed responses to the RFI questions. Note that we will use the term health IT to mean provider-focused health IT and only where we need to reference other health IT as, e.g., payer-focused health IT.

Functional Capabilities for Electronic Prior Authorization (ePA) in Certified Health IT (CHIT)

ONC Question: *What functional capabilities for ePA should be considered for inclusion in CHIT? What would be the core set of capabilities that would enable CHIT to:*

Identify when prior authorization is applicable for an item or service, using clinical decision support and/or user input, and for receiving notifications of changes in such applicability;

EHRA Feedback: We agree with the general capability statement but note that this capability may be achieved using both the initiating system (e.g., EHR) and another health IT system (e.g., a SMART App).

Query a payer API for prior authorization requirements for each item and service and identify in real-time specific rules and documentation requirements;

EHRA Feedback: We agree with the general capability statement, but we note that the EHR may not be the health IT system that requests such data from the payer, while the payer's technology is the system that identifies and communicates the documentation requirements to the health IT (e.g., a SMART App).

Collect clinical and administrative documentation needed to complete prior authorization documentation (electronic forms or templates) from a health IT system;

EHRA Feedback: We agree with the general capability statement, however, the source data may not be only in the initiating system (e.g., a scheduling system) and may rely on multiple/different sources. As described further below, guidance on what data access capabilities and data sources have to be queried for information should be part of the implementation guidance.

Electronically submit completed documentation for prior authorization to a payer's API, along with supporting information;

EHRA Feedback: We are concerned with a capability requirement for the submitter to final review and e-sign the supporting information being submitted, particularly when the aim is to enable, as much as possible, an automated flow that includes data collection and submission. Instead, we suggest that transparency and agreement to the data being collected will aid in automation.

Receive a response from a payer regarding approval, denial (including a reason for denial), or need for additional information;

EHRA Feedback: We agree this is an appropriate capability in the prior authorization workflow. It is also an example of a step that is typically considered an administrative process for which the clinical system needs, at most, only to receive the final status, as it may impact subsequent clinical decision making and care planning.

Query a payer's system for updates on a pending prior authorization request and have a reason returned as to why a request is still pending;

EHRA Feedback: We agree with the general capability and suggest this be clarified to include both the provider and consumer perspective, and the need to update various parties as a part of the workflow within a provider organization beyond the initiating clinician.

We also note that the term “pending” within the context of this capability does not have the same meaning as is in the suggested implementation guides. Alignment between this capability definition and applicable implementation guides is important to ensure clarity. It will be important to understand where in the process it is determined that additional information is needed, and what the required information is. A simple status change to pending would not adequately convey this, nor would it differentiate between waiting for information that is being collected and stating that additional information is needed with an indication of what that additional required data is.

Effectively capture and persist digital signatures (or other indications of provider review and assent), enable data integrity of documentation over time, and support other features necessary to meet payer administrative requirements associated with prior authorization transactions.

EHRA Feedback: We have concerns with this capability, as it seems to require a review and signature step by the initiating clinician attesting that the supporting information being sent with the prior authorization request is accurate and complete. We note that current capabilities of CHIT for user access controls and audit capabilities already enable us to validate the source of the data.

Attesting to completeness would not be appropriate as subsequent data requests are common and often unpreventable, even when the initial request was fully responded to.

Additionally, with the intent of automation to reduce or eliminate user interactions to collect prior authorization data, the system would often be compiling available data per payer requirements to support ePA requests downstream of its initial recording in clinical workflow, typically well after any provider verification or signature step of medical record entries. A review and signature step would therefore re-introduce user interaction where it is unnecessary, increasing documentation burden and creating unintended consequences such as delays and denials.

We recommend that this not be required as a separate prior authorization capability, but rather consider the requirement supported by proper implementation of user access controls to assure verified user identity for the sake of the original recording of medical record entries and auditing capabilities of CHIT.

ONC Question: *Are the above appropriate minimum capabilities needed for CHIT systems to successfully interact with payer systems to complete ePA activities?*

EHRA Response: In addition to the comments above, we provide the following feedback:

One of the challenges for health IT is to identify for a health plan what the endpoint is for each payer-focused health IT that may support one or more prior authorization workflow steps. We recommend a directory capability of health plan endpoints where there is a single endpoint for each health plan that resolves the appropriate routing for the respective payer health IT and supports that certified interaction.

We generally note that these capabilities, using APIs based on the Da Vinci implementation guides, are in the very early stages of development, maturation, and deployment - many payer

health IT do not support any of these APIs. An ONC certification approach, in combination with appropriate policies by CMS, will be critical to advance electronic prior authorizations while enabling provider and payer health IT systems to be ready to support their part. Realistically, full certification across all relevant health IT will take time, as the necessary experience and maturation to have an unambiguous and appropriately granular approach that can work across all health IT do not yet exist.

We suggest that functional capabilities for ePA should be clarified to include the ability to capture additional data if the initial prior authorization request is subsequently deemed to be lacking required information.

We want to emphasize that these capabilities need not be supported by a singular health IT solution on either the provider or payer side. Therefore, any implementation guides and associated certification criteria must be sufficiently granular so as not to require health IT to support more than is necessary to successfully be part of an automated prior authorization workflow. Health IT may include SMART Apps that take on significant aspects of this flow as well.

We recommend that given the current lack of clarity on how these capabilities can be distributed and enabled across health IT, that any consideration of policies and certification criteria follow a staged approach as suggested in our General Considerations and Recommendations section.

Implementation Specifications to Support ePA Capabilities

ONC Question: *What information can you provide on the three identified Da Vinci Implementation Guides (IGs) that would address questions or concerns that ePA workflow can be supported appropriately by them?*

EHRA Feedback: Regarding the three suggested Da Vinci implementation guides we offer the following considerations:

General – Generally the guides provide a sufficient starting point to implement the variety of interactions across the full prior authorization workflow. However, unless one has been part of development, testing, and/or initial deployment, it is not clear from the guides which interactions are sufficient to be supported by the variety of health IT that can be involved in the prior authorization workflow. This is attainable, starting with the current ballot cycle of the three implementation guides, but needs more maturation for the provider-focused interactions before it is ready to be used by certification criteria and their associated tests.

CRD – This guide should address the step of initiating a SMART App, when presenting separately from the direct interaction with the payer to get the actual coverage determination. Initiating the SMART App is commonly accomplished using CDS Hooks (including sufficient information), but a simpler initiation of the SMART App where that app then gathers any missing information using FHIR US Core + Coverage based APIs has been demonstrated to work as well. If a simpler approach is considered, thus a CDS Hooks is not used to initiate the SMART App, a notification mechanism is required informing the initiating system what the determination is.

DTR – This is the more complex implementation guide as this involves more extensive workflow coordination in terms of accessing the appropriate data sources (of which there may be multiple) and requires some manual collection of data, handoffs, etc. to fully operationalize. The system that initiated the prior authorization workflow may not be the one that has the relevant data (e.g., the scheduling system started the process where the data is in the EHR and/or HIM). For automated data collection, the IG assumes the data source translates the CQL or Questionnaire into appropriate queries and puts it into the QuestionnaireResponse. In practice, a SMART App may take the CQL or Questionnaire and translate it into FHIR US Core-based queries to the source systems. Thus, source systems may only need to support FHIR US Core, not any of the DTR capabilities.

This would also be the implementation guide to provide more guidance on any review and signature requirements. We note, however, that we do not support that capability requirement as discussed in response to the first survey question.

PAS – This guide covers three stages (submission, monitoring progress/status, and final authorization disposition), where the second stage of monitoring progress/status is of interest to systems other than the coordinating health IT, (e.g., initiating system, consumer app, and for the final determination the back-office or revenue cycle health IT). Those status interactions should therefore be a separate building block within the guide. Additionally, the use case of requesting additional data is not yet in a published version (it is in ballot). That area also needs further definition on how the additional data needed is identified by the payer.

While many of the interactions needed are addressed in the Da Vinci implementation guides, how they can be used across various health IT is not sufficiently recognized. That makes it challenging for a certification program enabling not only a single health IT solution supporting the prior authorization workflow, but also enabling multiple health IT together in the prior authorization workflow. Establishing more granular interaction sets, or building blocks, that can be used between multiple health IT is critical for the guides to be used for a successful certification program.

The complexity also indicates the need for health IT used by all actors in the flow to be considered for certification to ensure that interactions are consistently enabled, regardless of which system is on the other side (provider and payer).

We recommend that the approach suggested in the General Considerations and Recommendations section be adopted to provide a glidepath towards full deployment of automated prior authorization.

Additional Approaches to Support ePA Healthcare Attachments

ONC Question: *What perspectives do you have on the HL7 C-CDA R2 Attachment Implementation Guide (CDA Attachments IG) or the HL7 FHIR Document (FHIR Documents) section of the FHIR Release 4 standard as the basis of a healthcare attachment standard as a part of the prior authorization workflow for provision of medical records in support of ePA?*

EHRA Response: The HL7 C-CDA R2 Attachment Implementation Guide is not a widely used guide, and FHIR Documents are not yet on the roadmap of many EHRs to provide supporting information for a prior authorization. Considering that, one may think that skipping a C-CDA document based approach and

going directly to a FHIR Document to align with the FHIR-based approach in PAS for supporting information would be a sensible path to follow. Both a C-CDA and FHIR-based approach would require new efforts by CHIT developers to express the supporting information in that format. However, a more fundamental question should be whether there is a need for a document-based approach for the supporting information for a prior authorization request. The PAS guide is silent on the use of using a document to capture all data; rather, it allows for including documents and data as available. We note that such an approach is reasonable and eliminates an unnecessary translation step from the source data to such a document. As the necessary data is being collected using FHIR-based APIs, it can be included in the Questionnaire Response or even directly in the PAS Claim.

We therefore suggest to neither require a new C-CDA nor a FHIR-based document solely for the purpose of packaging the data as an “attachment”. IF there is a need in the transition to an X12 transaction to have such a document envelope, we suggest using a FHIR Document format.

***ONC Question:** What other additional areas should ONC consider in supporting the exchange of healthcare attachments in prior authorization workflow?*

EHRA Response: As indicated in our response to the e-signature capability, we reiterate our concern for requiring a review and signature when automating the data collection, as it introduces an extra human step to the process. Similarly, formatting the source data into an attachment introduces additional automation steps without any clear additional value. We also note that if the C-CDA document format is chosen, that means that many readily available C-CDA documents would require updates to meet the guidance referenced. While we believe the better longer-term direction is FHIR Documents generally, it would be better to avoid requiring new C-CDA document types for packaging purposes only.

***ONC Question:** What potential intersection exists with other administrative, and operations processes that ONC should consider when exploring options for healthcare attachments? How should ONC harmonize these efforts?*

EHRA Response: We note that the term “attachments” is used for a variety of data sets in support of a variety of payer-focused workflows. Where “attachments” are interpreted as “documents”, we urge policymakers to consider that with the transition to FHIR, “documents” need not be used just to package data for transport purposes, particularly when the recipient intends to automatically process it and can reasonably format FHIR-based data as appropriate to the purpose at hand. Such an approach could also support other HIPAA administrative transaction use cases, including claims, as well as other payer interests in medical records for payment audit, utilization review and risk scoring of beneficiaries, as examples.

***ONC Question:** Are there other standards initiatives, pilot projects, or health IT resources ONC should explore to identify promising best practices, emerging standards, or other innovative approaches to advance interoperable health IT for healthcare operations use cases?*

EHRA Response: We have no specific feedback.

Certified Health IT Functionality

***ONC Question:** Do the functional capabilities described above include all necessary functionality for certified Health IT Modules to successfully facilitate electronic prior authorization processes? Are there*

additional capabilities that should be included in certified Health IT Modules to address these needs? Should any of these functional capabilities not be included in certified Health IT Modules (please cite the reason they should be excluded) or should ONC focus on a more limited set of functional capabilities for certified Health IT Modules than those described above?

EHRA Response: Generally, the functional capabilities cover the overall prior authorization workflow, although, as indicated in prior responses, there are some areas that are missing (e.g., consumer-focused query ability for prior authorization status updates). There is also a need for recognition by ONC that the capabilities can be supported by multiple forms of health IT on the provider and/or payer side, thus requiring a more modular, granular certification approach.

ONC Question: *Should ONC adopt a certification criterion for prior authorization that accounts for the full, HIPAA compliant workflow for prior authorization transactions including translation from FHIR to the X12 standard? Or should ONC adopt certification criteria that include only the workflows up to the point of translation? What ongoing challenges will stakeholders face if there is a need to translate between HIPAA-adopted standards and other standards that have only been adopted under the Certification Program used to support prior authorization transactions? How should HHS address alignment between standards adopted for HIPAA transactions and standards adopted under the Certification Program?*

EHRA Response: We suggest that the ability to translate in/out of X12 is addressed as a separate capability that could be certified, but not as a part of the FHIR flow. This would allow the capability to be easily isolated and utilized by the specific health IT module responsible for that translation. Provider-focused health IT need not have such specific capabilities as they do not operate in the X12 transaction space. Intermediaries may already have the necessary capabilities to address that translation and transmission. Additionally, ONC should **not** adopt a singular ePA criterion that embraces all the capabilities necessary for the full ePA workflow nor all of the interoperability requirements to support the same. The market reality is that many provider organizations obtain various clinical, administrative, and revenue cycle health IT from different sources, and while many software developers may offer both types of products and could certify them in combination, providers do still adopt health IT from different suppliers and need to be supported with the availability of certified health IT matching that reality. Additionally, the availability of SMART Apps and intermediaries that enable various stages of the process (e.g., interaction with payers for coverage determination, documentation requirements, and submission) would not require an EHR to support most of the capabilities, but rather only the need to initiate the workflow and to be notified of key status changes. Therefore, ONC should allow for the discretion of the health IT developer to be exercised to certify to some or all adopted ePA criteria.

ONC Question: *If ONC were to propose to include these functional capabilities as part of the Certification Program, how should a new certification criterion (or multiple certification criteria) be structured, including technical requirements, attributed standards, and implementation specifications? ONC's experience adopting certification criteria suggests that, at times, combining related functions into a single health IT Module is most appropriate, while in other cases, health IT functionalities are best represented by separate certification criteria, despite being functionally related. For instance, under a single criterion, different products and services in the market may be "tightly coupled" for the purposes of certification, even when they can be purchased and implemented separately. We seek the public's input on which functional capabilities for prior authorization should be tested and certified together as part of one certification criterion, and which capabilities should be separated into different certification criteria.*

EHRA Response: We suggest that the current Da Vinci implementation guides individually or together would yield too coarse of a certification criterion that a single health IT solution for either provider or payer use should support in full to be certified. Rather, a more granular set of interaction building blocks should be established by the community in collaboration with ONC where individual health IT solutions can select the applicable criteria that they can fulfill as part of a health IT configuration that could include other software to support the full array of interactions. This is particularly important to start the introduction of a more automated and integrated prior authorization workflow into provider and payer use. We do provide in the General Considerations and Recommendations a suggested staged approach in which certification criteria for health IT is introduced in Stage 2 after sufficient experience and maturity has been attained in the deployment of the necessary building blocks. We further suggest that the current ballot cycle of the three Da Vinci implementation guides can already be used to establish an initial interaction set upon which certification criteria for the respective actors could be based as the maturation process begins through actual implementations and deployment.

Implementation Specifications for Prior Authorization

ONC Question: *What is the current readiness of the three FHIR-based Da Vinci IGs described above for adoption as part of certification criteria for health IT? Given limited testing of these specifications to date, what would be a feasible timeline for use of these IGs in production for prior authorization transactions? What, if any, additional changes are needed for these IGs prior to adoption as part of certification criteria for health IT?*

EHRA Response: Deployed solutions are very limited, but initial rollout has begun by some health IT suppliers (including payers) using SMART Apps.

We outlined in the General Considerations and Recommendations section a phased approach whereby payer health IT use would be done first using certification against the existing Da Vinci implementation guides before being made available for use by provider health IT developers; this would allow calibration of the interactions between the Da Vinci IGs and payers, and provide opportunity for further analysis as to how to best interact across the necessary health IT systems in use. That phase should not immediately require health IT certification. This allows experience to be gained by payer health IT implementations using the Da Vinci implementation guides to provide a natural common target against which to develop. Note that this is quite similar to EHRs being certified to the FHIR US Core APIs while the applications connecting to those APIs are not at this time. We furthermore suggest that the focus is on the initial CRD and PAS implementation guides, as the DTR IG will involve more complexity and learning to ensure a clear, integrated workflow. This approach for DTR would not need to stop progress given that health IT can already start to connect to payers for DTR when the relevant payer health IT source is already certified. Again, this is akin to the current process of FHIR-based APIs on EHRs being gradually and increasingly utilized as applications' capabilities are being expanded.

ONC Question: *If the existing IGs are not yet ready for adoption, should ONC still propose certification criteria? Should ONC consider proposing certification criteria incorporating the FHIR Release 4 base standard but delay adopting implementation specifications until a later date? What are the potential risks of this approach?*

EHRA Response: We do not support any certification criteria that would require support of FHIR R4 or any other FHIR core standard version. Such an approach would yield substantially variant approaches

and implementations that would make it impossible to create a working prior authorization workflow across multiple provider and payer health IT systems with 1500+ variant health plan rules. We suggest that our proposal in the General Considerations and Recommendations section provides an anchor around a payer-supported set of interactions defined in the three Da Vinci implementation guides that health IT developers can use as their target for implementations. We believe that these payer health IT-based APIs for the respective interactions can also be further clarified through the existing Da Vinci implementation guides upon which certification criteria can be based, while those for use by provider health IT-focused certification criteria be phased in at a later stage as outlined in the General Considerations and Recommendations section.

ONC Question: *If we were to adopt certification criteria referencing the base standard and then update those criteria to integrate implementation specifications in the future, how should these integrations be handled? When and how should the existing systems be replaced? All at once, or as a series of transitional steps?*

EHRA Response: As indicated above, we do not support using the FHIR R4 base standard as a reference for implementation. Rather the Da Vinci implementation guides, in combination with the SVAP process, provide a path forward as long as there is no requirement for a singular health IT solution to cover all interactions. This also requires that certification for health IT is phased in once the appropriate level of interaction between building blocks has been established and validated through mature implementations.

We do not believe that the approach that ONC took to the original 2015 Certification Edition (where it did not specify a specific standard) would be viable, either, as then even more variations would likely emerge that cannot interoperate. Effectively, Da Vinci has done the type of work that Argonaut did using FHIR DSTU 2 and demonstrated the value of a common interpretation to start.

ONC Question: *Do the Da Vinci IGs effectively support Federal and state legal requirements and/or health plan compliance requirements for clinical documentation, for example, signatures (or other indications of provider review and assent), record retention over long periods of time, and document security to ensure data integrity once stored?*

EHRA Response: Generally, we suggest that an interoperability implementation guide specifies functional requirements of the respective systems for capabilities such as data retention durations, signatures, security, and integrity. Where needed, those should be addressed separately as general system requirements that are not unique to prior authorization and/or interoperability that for the most part already should be in place. Regarding signatures, we note our comments on the e-signature capability that we are concerned with such a requirement in light of automated data collection and already available user access controls, audit log and security for certified EHRs. We would suggest that those relevant certification criteria primarily focus on non-EHR health IT to ensure that fundamental capabilities are in place.

ONC Question: *What alternative approaches to designing certification criteria should ONC explore that are not based on the three Da Vinci IGs described herein?*

EHRA Response: An alternative approach to any certification-based approach would be for the industry to rally around the Da Vinci process on a voluntary basis, not driven by the need to certify, and continue to progress efforts and demonstrate success based on CMS policy-driven incentives to spur advances in prior authorization. That may be seen as a challenge in light of numerous competing priorities, but we

also must urge ONC to be considerate about the resources necessary to progress and advance the many other capabilities, not subject to certification, that our clients are requesting.

ONC Question: *Are there simplified approaches to the workflows described in the Da Vinci IGs that ONC should consider as alternative approaches to support electronic prior authorization?*

EHRA Response: While there are opportunities to reduce the need for prior authorizations depending on the level at which authorizations are determined (e.g., item, condition, or population), once a prior authorization is required, the workflow is essentially as described. That means that optimization must be found in the ability to easily collect the relevant data automatically. Simplification of rules and expressing those rules based on discrete data electronically available, akin to the approach followed in the progression of eQMs and eQMs, should be considered. We note that another way to simplify the workflow is to arrive at fewer requirements for more granular prior authorization with more emphasis on general (chronic) conditions that imply certain authorizations.

ONC Question: *Are there new IGs which need to be developed in order to integrate with other workflows relevant to prior authorization? In particular, what IGs may still need to be developed in order to integrate with HIPAA administrative transaction standards?*

EHRA Response: We suggest that targeted guidance for the following capabilities would be helpful:

- consumer apps to obtain an authorization status (including being made aware of the existence of a prior authorization having been submitted)
- translation in/out of X12
- notification of coverage requirement determination outcome to the initiating system
- notification of the authorization request to the initiating system and other interested systems
- payer/health plan endpoint directory for respective interactions

Healthcare Attachment Standards

ONC Question: *Would the specifications within the CDA Attachments IG, if adopted as part of a certification criterion, support more effective exchange of healthcare attachments for prior authorization? Would any changes to the IG be needed, or would additional functionalities or standards be required for effective implementation of the CDA Attachments IG in certified health IT?*

EHRA Response: We suggest that the introduction of an extra transformation step to populate the PAS prior authorization request is not necessary. The concept of a “document” does not have real value for packaging purposes. The need for review and signature in an automated data collection approach, which could validate the use of a “document,” should not be required either as it would serve to create additional burden and delay the process unnecessarily. Rather, we recommend that the approach already included in the PAS implementation guide that effectively enables attaching individual data points as well as documents of various kinds (e.g., C-CDA, FHIR, .pdf), which does not require a dedicated C-CDA based document for packaging healthcare attachment data.

ONC Question: *Would the use of FHIR Documents, if adopted as part of a certification criterion, support more effective exchange of healthcare attachments? Are there any gaps or constraints that would need to be further specified, such as through an IG, in order for FHIR Documents to be effective for this use*

case when implemented in certified health IT? Would the adoption of a certification criterion for FHIR Documents support other administrative use cases beyond prior authorization?

EHRA Response: We suggest that the introduction of an extra transformation step to populate the PAS prior authorization request is not necessary. The concept of a “document” does not have real value for packaging purposes. The need for review and signature in an automated data collection approach, which could validate the use of a “document,” should not be required either as it would serve to create additional burden and delay the process unnecessarily. Rather, we recommend that the approach already included in the PAS implementation guide that effectively enables attaching individual data points as well as documents of various kinds (e.g., C-CDA, FHIR, .pdf), which does not require a dedicated C-CDA based document for packaging healthcare attachment data.

ONC Question: *Given limited testing of these approaches to date, what would be a feasible timeline for use of the CDA Attachments IG or FHIR Documents in production for prior authorization transactions?*

EHRA Response: Considering we do not see the value of introducing a document into the prior authorization flow, we do not have a specific timeline that we think this would (or should) take. We do suggest, however, that this would add substantial effort that could better be focused elsewhere. Rather, we recommend that the approach already included in the PAS implementation guide that effectively enables attaching individual data points as well as documents of various kinds (e.g., C-CDA, FHIR, .pdf), which does not require a dedicated C-CDA based document for packaging healthcare attachment data.

ONC Question: *Which of these approaches would better accommodate improvements over time to meet payer and provider needs? Should ONC consider adopting certification criteria referencing one approach over the other, or should ONC consider supporting both approaches within certified health IT?*

EHRA Response: We suggest that submission of data sets (a combination of individual data, C-CDA or FHIR documents, and other non-structured documents that are relevant and available) be permitted as the current PAS implementation guide would support. We do not support the required translation into or creation of a document where a document otherwise did not exist.

ONC Question: *If the IGs developed by the Da Vinci Project, or an alternate set of IGs addressing the full scope of prior authorization workflows, are not yet ready for adoption in certified health IT, should ONC propose certification criteria to support healthcare attachments transactions for prior authorization alone?*

EHRA Response: We do not support the focus on introducing a document-based approach for the supporting information where the Da Vinci approach of using a data set approach is very appropriate in an automated prior authorization workflow in which the relevant data is automatically retrieved by clearly defined, transparent documentation requirements.

ONC Question: *Healthcare attachments are used for a wide range of operations and administrative workflows beyond prior authorization. Are either of the standards discussed above commonly used in other administrative or operations transactions? Would there be a burden or benefit to using either, or both, standards in light of other administrative or operations workflows? Are there additional standards or implementation specifications ONC should consider that are in common use for healthcare attachments used in other administrative or operations workflows?*

EHRA Response: We are not aware of wide-scale use of C-CDA or FHIR documents for prior authorization. Generally, we suggest that creating new documents solely for the purpose of packaging data in support of a prior authorization is not necessary where we are moving toward FHIR-based,

automated workflows that can include original source data points and/or documents as available and appropriate to provide the necessary supporting information.

Impact on Patients

ONC Question: *How could potential changes to the Certification Program to better support prior authorization positively impact healthcare consumers?*

EHRA Response: Generally, patients will benefit from improved prior authorization processes by reducing turnaround times and inefficiencies and instead accessing services and better transparency of service authorization requirements. This in turn can also allow for more provider-patient time to deliver care instead of spending time unnecessarily pursuing approval of prior authorizations. Patients may also be able to directly query payers and providers regarding the authorization status of pending requests, as well as research what services require prior authorization requirements on their own, which may also serve to reduce provider burden as it supports increased engagement by the consumer. A certification program can enable more consistent implementations of the interoperability capabilities necessary to support a complex workflow such as prior authorization across the variety of provider and payer health IT. A certification program can also hinder when it is initiated too soon because guidance is not yet mature, when not all actors in the workflow are all validated on their conformance but rather only one actor is, and the certification criteria are not yet right-sized to the participating health IT and their relevant interactions. Any of these scenarios would delay the roll-out and create confusion and missed expectations across all stakeholders.

ONC Question: *How could potential changes reduce the time for patients to receive needed healthcare services, reduce patient non-adherence, and/or lower out-of-pocket costs?*

EHRA Response: Patients would benefit from earlier insight into the financial impact of a planned/ordered service/procedure/medication and more immediate decision-making due to pending authorization requests. Additionally, an electronic workflow will increase transparency to the patient being able to have visibility to the progress and decisions by the payer, as well as an opportunity to have further insight into the decision-making rules. In combination with the forward sharing of a patient's record as they change payers, as required by recent CMS rules, authorizations for ongoing, chronic care can be streamlined reducing uncertainties around ongoing treatment needs. We suggest a next stage for payers to consider using the patient's prior record upon intake to proactively inform the providers of "pre-approved" prior authorizations for continued care.

ONC Question: *Besides the provider to payer interactions discussed in this RFI, is there additional functionality that could be added to the Certification Program that would better support patients' participation in the prior authorization process?*

EHRA Response: We suggest that the interactions necessary for a consumer-focused app/portal to directly query payers for the status of in-process prior authorization requests should be considered. Similarly, having access to a directory of services/procedures/medications that require prior authorization would be helpful so one need not invoke a CRD to find out for one service at a time which ones require authorization. Such a capability could enable an initiating system as well to not invoke CRD for every service/procedure/medication being ordered. Finally, spurring support for the portability of open approved authorization requests should a patient change health plans, for transcending a health plan year where new authorizations may be required each year under current health plan rules and

supporting requiring only a single authorization for recurring service series as a whole or at the episode level would make for a much more consumer-friendly experience for beneficiaries.

Impact on Providers

ONC Question: *To what degree is availability of electronic prior authorization capabilities within certified health IT likely to reduce burden for healthcare providers who currently engage in prior authorization activities?*

EHRA Response: We suggest that if we can effectively reduce the time from needing an authorization to having a decision (automatically initiating the workflow, gathering most/all data automatically, and minimal user-based data reviews/sign-off), we would see a significant improvement in terms of timely clinical decision making, resource utilization to obtain an authorization, reduced uncertainty on the progression of care.

Adoption of electronic prior authorization capabilities promises to reduce the administrative steps necessary to obtain authorization compared to the current semi-automated processes while enhancing the transparency of requirement for when authorization is needed, substantiated by what documentation, and improve payer responsiveness (and usefulness of response) and clarity of response, thus providing for better integration with provider workflow. As ONC has noted in its own report on the burden of EHR use, some physicians report spending an inordinate amount of their own practice time engaging in these activities, which contributes to their own sense of burnout. Payers also should take steps to make requirements transparent to enable providers to authorize the automatic collection of the necessary data and submission of the request without additional human review.

ONC Question: *To what degree are healthcare providers likely to use these new capabilities across their patient panels? Will additional incentives or requirements be needed to ensure healthcare providers effectively use these capabilities? What accompanying documentation or support would be needed to ensure that technology capabilities are implemented in ways that effectively improve clinical workflows?*

EHRA Response: The potential benefits of electronic prior authorization also present a significant incentive for adoption due to the promise of lower operating costs, reduced provider burden, and enhanced transparency of authorization requirements. That adoption would be enhanced by broadening payer support for reducing the necessity for authorization of individual services when authorization can be had once for recurring service and episode level use cases.

In response to ONC's draft version of its report ***Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs***, suggestions were made that ONC and CMS should collaborate with the payer industry to determine if "simple" authorization use cases could emerge where approval could be more easily adjudicated or even automated given the context of the service. All these factors provide an opportunity for burden and operating cost reduction and may serve as incentive enough for use. Also, the ease of use of these capabilities for providers will enhance adoption, especially the extent to which there is the ability to collect the relevant supporting information automatically based on a well-defined transparent scope of such data provided by payers. Much of this depends on the support given by payers.

At the same time, considering the complexity, maturity of standards, and variety of health IT that needs to be connected, not all of the workflow can be expected to be in place in one phase. In the General Considerations and Recommendations section, we provide a staged approach that can enable wide uptake of initial capabilities and expand to full workflow support after that.

For the staged approach to be successful, implementation for providers should focus on bundling similar clinical contexts together as functionality is rolled out to ensure that prior authorization processes are done consistently based on clinical context. Phasing similar procedures or medications at different points instead will create additional friction for providers which may slow uptake and adoption.

Impact on Developers

ONC Question: *What estimates can health IT developers share about the cost and time (in hours) of developing electronic prior authorization functionality within certified health IT products?*

EHRA Response: We do not have this information available across our members.

ONC Question: *What factors would inform the burden for health IT developers to develop certified Health IT Modules for electronic prior authorization based on the three Da Vinci IGs described above?*

EHRA Response: As outlined above, taking a coarse certification approach and starting certification for health IT before the appropriate level of granularity has been established and matured through operational experience would impose substantial burden on EHR developers who would have to implement all the capabilities in one phase and coordinate with other health IT involved in the prior authorization workflow. In particular, the DTR capabilities would cause challenges, as they require management of data collection requirements across 1500+ health plans and coordination of any automation across multiple sources, as well as necessary manual follow-up. Those are administrative processes that typically do not fall within the scope of an EHR, as opposed to other administrative capabilities. Clearly, EHRs are prime sources for the necessary supporting information that can be progressively supported by FHIR US Core-based APIs relevant to EHRs.

ONC Question: *What would be the burden on health IT developers for prior authorization certification criteria referencing the base FHIR standard if there were not yet specific IGs adopted as well? How would potentially moving to criteria with use case-specific IGs over time impact development burden? Would such a staged approach be detrimental or beneficial to the long-term development timeline and burden for health IT developers seeking to support electronic prior authorization?*

EHRA Response: Considering the complexity and cross-health IT dependencies of the prior authorization workflow we suggest that an approach that is based on the core FHIR standard will increase effort, ambiguity, and misalignment as the necessary health IT would not have a clearly defined communication method for all the relevant data interactions. We suggest that the approach outlined in the General Considerations and Recommendations section provides a path to evolving the necessary support in a manageable set of steps where each of the relevant health IT can advance and focus their contributions.

Payer Implementation

ONC Question: *How could the Certification Program support the technology needs of healthcare payers in implementing electronic prior authorization? Should ONC consider payer workflows in the*

development of certification criteria to support the potential use of certified Health IT Modules by healthcare payers? Would the availability of certified Health IT Modules supporting these workflows reduce the burden for healthcare payers of engaging with healthcare providers in prior authorization processes?

EHRA Response: While we defer to the payers to provide further input, we suggest that it is critically important to consider the full prior authorization workflow across provider and payer health IT solutions, not just the health IT used by the provider organizations, and in that context that any certification program should include requirements for all.

ONC Question: *To what extent would healthcare payers be likely to use these certified Health IT Modules if they were available? To what extent are health IT developers likely to seek certification for Health IT Modules supporting payer workflows if these certification criteria were available?*

EHRA Response: We defer to payers to provide further insight into the question while repeating our response to the prior question.